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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,395	12/01/2003	Maryellen L. Giger	246027US-20	8891

22850 7590 02/01/2007  
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.  
1940 DUKE STREET  
ALEXANDRIA, VA 22314

EXAMINER
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TABATABAI, ABOLFAZL

ART UNIT	PAPER NUMBER
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2624

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/01/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/724,395

Applicant(s)

GIGER ET AL.

Examiner

Abolfazl Tabatabai

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Claim Rejections - 35 USC § 101**

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows:

Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.

When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and *Warmerdam*, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with *Warmerdam*, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).

In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See *Lowry*, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

2. Claim 7 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claim 7 defines a computer program embodying functional descriptive material. However, the claim does not define a computer-readable medium or memory and is thus non-statutory for that reason (i.e., "When functional descriptive material is recorded on some

computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized” – Guidelines Annex IV). That is, the scope of the presently claimed a computer program, can range from paper on which the program is written, to a program simply contemplated and memorized by a person. The Examiner suggests amending the claim to embody the program on “computer-readable medium” or equivalent in order to make the claim statutory. Any amendment to the claim should be commensurate with its corresponding disclosure.

### **Claim Rejections - 35 USC § 102**

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Nishikawa et al (U S 6,058,322).

Regarding claim 1, Nishikawa discloses a method of analyzing a medical image to arrive at information concerning a disease that may be evidenced by a lesion in the medical image, the method comprising:

extracting at least one lesion feature from the medical image (please note, to column 32, lines 4-15); and,

arriving at the information concerning the disease (please note, to column 30, lines 26-29), based on non-parametric estimation of the distribution of the feature (please note, to column 20, lines 18-24 and column 32, lines 4-15. Artificial neural networks are non-parametric analysis circuit and is one of several statistical methods includes linear discriminant analysis, K nearest neighbors, etc. The advantage of the ANN over other methods is that is a non-linear technique. Thus, ANNs have a greater potential in solving complex and incomplex problems as compared to other statistical methods) over the database (please note, to column 22, lines 15-19).

Regarding claim 2, Nishikawa discloses the method of claim 1, wherein the information comprises at least one from a group including:

- a decision on whether a lesion is present in the medical image (please note, to column 32, lines 8-12);

- a characterization of a likelihood that the lesion is malignant (please note, to column 32, lines 8-12);

- a characterization a stage of cancer of the lesion (please note, to column 30, lines 23-29);

- a characterization of the lesion as being malignant or benign (please note, to column 8, lines 47-50); and,

- a characterization of a likelihood that a malignancy will develop in the future (please note, to column 32, lines 12-15).

Regarding claim 3, Nishikawa discloses the method of claim 1, wherein the risk

feature extracting step comprises:

analyzing a surrounding environment of the lesion (please note, to column 21, lines 66-67 and column 22, lines 1-10).

Regarding claim 4, Nishikawa discloses the method of claim 3, wherein the analyzing step comprises: assessing a parenchymal pattern (please note, to column 4, lines 40-46) surrounding the lesion in human breast tissue in a mammogram constituting the medical image (please note, to column 9, lines 64-67).

Regarding claim 5, Nishikawa discloses the method of claim 1, wherein the lesion feature extraction step comprises:

determining at least one feature from a group of features comprising skewness of gray-values, spiculation, margin definition, shape (please note, to column 17, lines 32-37), density (please note, to column 33, lines 17-20), homogeneity (please note, to column 30, line 47), texture, asymmetry, and temporal stability.

Regarding claim 6, Nishikawa discloses a system implementing the method of claims 1, 2, 3, 4 or 5 (please note, to column 4, lines 59-65 and column 8, lines 9-12).

Regarding claim 7, Nishikawa discloses a computer program product storing program instructions for execution on a computer system, which when executed by the computer system, cause the computer system to perform the method recited in any one of claims 1, 2, 3, 4 or 5 (please note, to column 8, lines 25-33).

### **Other prior art cited**

5. The prior art made of record and not relied upon is considered pertinent

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to applicant's disclosure.

Huo et al (U S 6,282,305 B1) disclose method and system for the computerized assessment of breast cancer risk.

Giger et al (U S 5,657,362) disclose automated method and system for computerized detection of masses and parenchymal distortions in medical images.

Doi et al (U S 5,790,690) disclose computer-aided method for automated image feature analysis and diagnosis of medical images.

Rogers et al (U S 5,999,639) disclose method and system for automated detection of clustered micro calcifications from medical mammograms.

### **Contact Information**

6. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to ABOLFAZL TABATABAI whose telephone number is (571) 272-7458.

The Examiner can normally be reached on Monday through Friday from 9:30 a.m. to 7:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Mehta Bhavesh M, can be reached at (571) 272-7453. The fax phone number for organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published

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applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Abolfazl Tabatabai

Patent Examiner

Technology Division 2624

January 25, 2007

*A-Tabatabai*